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To: Senator Emil Jones, III, Illinois State Senate
From: Malaysian Rubber Export Promotion Council (MREPC)
Re: Opposition to HB2831 Food Service Ban-Latex Gloves



While the intent behind HB2831, to protect those suffering from latex allergies, is commendable, enacting this legislation may be an unintended disservice to the safety of public health. Therefore, MREPC would like to share with you several important points regarding the proposed course of action.

## 1. Changes in Latex Glove Manufacturing: Improved Low-protein, Powder-free Gloves

Latex allergies were first reported in healthcare settings in the late 1980s and 1990s due to repeated exposures to an **older generation of latex gloves** containing high levels of residual proteins, some of which were allergenic to certain sensitive individuals.<sup>(1)</sup> However, due to advancements in glove manufacturing technologies, **today's new low-protein powder-free gloves have drastically reduced protein content** and many hospital studies in the U.S., Europe and Canada have shown that the **use of low-protein powder- free gloves has markedly reduced** sensitization and the incidences of allergy in the work place while still providing effective barrier protection. <sup>(2)</sup>

Additionally, when using the improved, low-protein, powder free latex gloves, healthcare professionals can now work alongside their latex sensitive workers with no serious incidences of allergic reactions. Therefore, rather than eliminate latex glove entirely, latex sensitive individuals are recommended to use latex-free gloves at all times, such as the nitrile gloves, which have reasonably comparable barrier capability as latex gloves.

The positive impacts of low-protein latex gloves leading to the decline in latex allergy incidences have been acknowledged as early as 2005 by several renowned U.S. allergy researchers. Their findings are summarized below:

"Low-protein, powder-free gloves dominate the market and have reduced exposures in the healthcare setting" – Donald Beezhold (NIOSH) & Gordon Sussman (University of Toronto), Lessons Learned from Latex Allergy, Business Briefing: Global Surgery – Future Directions, September 2005.

"At that time (mid-1990s) latex allergy peaked, and 8% to 12% of people who used latex were sensitized to it. Now, that number is down to about 1%. This is mainly due to a change allergen content of the gloves." – Kevin Kelly, (Chair of the Latex Allergy Committee for the American Academy of Asthma, Allergy & Immunology), Health Link, Medical College of Wisconsin, August 2005.

"Healthcare workers shown to be latex-sensitive were therefore provided with non-latex gloves, and their co-workers with low or non-powder latex gloves" .... "These maneuvers have reduced the prevalence of new latex-sensitive patients to a minimal degree and it appears that the epidemic has been eliminated." — Jordan N. Fink, Professor of Pediatrics, Allergy Division, Medical College of Wisconsin, and Business Briefing: Global Surgery- Future Directions, September 2005.

It should be noted that the above cited researchers attribute the decline of latex allergies to the availability of the improved latex gloves with vastly reduced residual protein/allergen levels.

While there are some individuals with a latex allergy, that population is only about 1% of all individuals who come into contact with latex gloves. Because there are other options for preventing latex allergies, as in simply providing allergic individuals with synthetic gloves, the Senate is not adequately supporting its plan of action.

## 2. Completely Replacing Latex Gloves with Synthetic Gloves is Not the Solution

#### Protection against Foodborne Illnesses:

Workers wear gloves in the food industry to protect food consumers against infectious microorganisms or other contaminants on wounded or inadequately washed hands of food handlers. Such contaminations could lead to serious foodborne illnesses, which have been estimated to cause about 130,000 hospitalizations resulting in 3000 deaths annually in the United States. (3)

However, it is important to note that not all food service gloves provide the effective barrier protection required to prevent the spread of foodborne illnesses. Among the commonly used gloves, namely, natural rubber latex, nitrile, vinyl and polyethylene gloves, the superior barrier performance of natural rubber latex gloves has been consistently demonstrated by numerous studies particularly compared to vinyl (PVC) and polyethylene (PE). (4)

Therefore, replacing natural rubber latex gloves with synthetic gloves with less effective barrier protection could undoubtedly increase the risk of food consumers being affected by foodborne illnesses.

## 3. Is Latex Allergy A Concern?

The issue of possible allergic reactions elicited via food ingestion has been examined thoroughly by the U.S. Food and Drug Administration ("FDA") when latex gloves with high powder and high protein contents were still commonly used.

For example, in April 2002, at the Conference on Food Protection ("CFP") – a powerful organization that profoundly influences model laws and regulations among all government agencies and minimizes disparate interpretations and implementation – the FDA reported that although the 75 self-reported cases of food- mediated latex allergies were received from consumers in late 2000 and early 2001, these cases "are not clinically verified through medical records and it is possible that some of the reactions described could have been due to consumption of foods that cross react to latex protein (e.g. kiwi, bananas, buckwheat, stone fruits, potatoes, tomatoes, sweet pepper, chestnuts, spinach, etc.)." The CFP concluded that there was much uncertainty about allergens being transmitted from latex gloves and their effects on consumers, and there was a need for more studies on this matter.

<u>Notes:</u> Cross-reactivity occurs when your body's immune system identifies the proteins in one substance (e.g. latex protein) and the proteins in another (e.g. fruit & vegetables) as being similar. When you come into contact with either, whether it is in the presence of the protein that you are truly allergic to or not, your immune system can react in the same way, which can then cause your allergic symptoms <sup>(5, (6))</sup>

Again, in August 2003, the Additives and Ingredient Subcommittee of the Food Advisory Committee to the FDA's Center for Food Safety and Applied Nutrition ("CSFAN") conducted a two-day hearing on this issue. After gathering and thoroughly examining information from independent experts and interested parties from the public, the Subcommittee reached a consensus and concluded: "The evidence is suggestive of a **weak positive relationship** between the use of natural rubber latex gloves and food-mediated latex allergic reactions. The data linking the presence of these [latex] proteins in foods to allergic reactions is based primarily on anecdotal evidence, and is very weak." (7)

It was concluded that there is insufficient scientific evidence that there is an unacceptable consumer safety risk if foods are prepared using latex gloves.

Furthermore, while one commonly referred to study attempted to show transfer of glove proteins to food, it is important to note that the study used the **older generation of latex gloves with high levels of latex proteins and high content of powder**. <sup>(8)</sup> Moreover, to exaggerate or emphasize the effect, the older generation gloves were also turned inside-out to expose the inner side of the gloves which were loaded with the protein carrier powder. Therefore, while the results so reported are not indicative of the normal food preparation practices as demonstrated in the foodservice industry today or reflective of the advanced low- protein, powder-free latex gloves, **the study did demonstrate that when gloves with low protein/powder content were tested, NO protein transfer was detected.** This confirms that the improved low-protein powder-free latex gloves should be the choice when latex gloves are used.

The need to eliminate the use of latex gloves in food establishments is not a necessity when low-protein powder-free gloves are used. Important to note here is there are no reported deaths caused by latex protein allergy through food ingestion, unlike in the case of milk, peanuts, fish served in food which have been estimated to cause death of more 150 allergic people annually in the U.S. particularly peanuts (9) Completely prohibiting the use of latex gloves, an effective food safety tool, could be a disservice to the public health.

#### 4. Dangers of toxic chemicals from synthetic gloves

Some **non-latex disposable food gloves can pose health hazards** for consumers and food workers. Many **vinyl** gloves, for example, are manufactured with highly toxic phthalates such as di (2-ethylhexyl) phthalate ("DEPH"), which makes vinyl soft and pliable. DEHP content varies between 22 and 41 percent of glove by weight. (10)

Of particular concern in food-contact applications is the fact that **DEHP can leach out of vinyl products**, such as disposable gloves, food containers and wrappers. DEHP is particularly soluble in fluids and oil- based products. It can easily contaminate liquids like drinking water and milk, or foods such as cooking oils, cheese, meat and fish. (11)

The dangers of DEHP are well documented in animal studies, which show it can cause testicular damage <sup>(12)</sup>, suppress or delay ovulation <sup>(13)</sup>, reduce kidney <sup>(14)</sup> and liver function <sup>(15)</sup>, and cause respiratory distress <sup>(16)</sup> and adverse effects on the heart <sup>(17)</sup>. Studies show that infants, children and pregnant women are much more sensitive than others to such adverse effects. In July 2002, the FDA warned "precautions should be taken to limit the exposure of the developing male to DEHP<sup>(18)</sup>."

Spurred by concerns about the health hazards posed by food handlers wearing vinyl gloves, Japan's Department of Food Sanitation, acting on a recommendation by the country's Ministry of Heath, Labor and Welfare, issued a directive in 2000 against the use of vinyl gloves with DEHP in food service kitchens (19).

The Ministry cited research by the Japan National Institute of Health Sciences demonstrating that "The DEPH in foods packed ... using vinyl gloves was found to increase drastically when compared with that of the foods before packing," and "the use of PVC [polyvinyl chloride] gloves with DEPH caused a sharp increase in the level of this chemical in foods (20)."

# 5. <u>Disposal and Environmental Impact of Synthetic Gloves</u>

HB2831 proposes to eliminate the use of latex gloves and seemingly replace them with synthetic gloves. However, the bill does not address the environmental impacts of such a course of action.

Natural rubber latex gloves are very environmentally friendly, as they are derived from trees. They are sustainable and also biodegradable. In contrast, latex-free or synthetic gloves are not, as they are mainly made from petrol chemicals, which may be carcinogenic or toxic. **Disposal of synthetic gloves, by burning, would release harmful substances, like dioxin, into the air, water and soil.** If disposed by landfill, these synthetic gloves would persist in the soil for years. In the meantime, the synthetic toxic chemicals would leach out poisoning the soil and groundwater.

#### Conclusion:

While we must be responsive to the needs of the small population of latex sensitive individuals, it is also very important that the vast majority of the population not allergic to latex, be provided with the excellent barrier protection of natural rubber latex gloves. This is now made possible with the availability of improved low-protein powder-free latex gloves. MREPC respectfully urges the Senate to note the stark differences between the old, high-powder, high-protein latex gloves with the improved low-protein, powder-free gloves.

Understandably so, allergies to proteins from natural rubber latex and from many foods, as well as the health and safety risks associated with the inferior glove barrier protection and chemical contaminations are important considerations for consumer protection and food safety.

The proposal to eliminate the use of latex gloves - an effective food safety tool - in food service establishments is not warranted. MREPC therefore respectfully request the Senate to take into consideration the above- presented information as you proceed with your deliberation of HB2831. We hope that the Senate can amend the bill to only prohibit high-protein, high-powdered latex gloves.

Thank you for taking time to read through our comments.

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The Malaysia Rubber Export Promotion Council (MREPC), is a Malaysian Government Agency, serving as an education and information center focusing on Malaysian rubber products, particularly gloves. Being the world's major supplier of gloves, both latex and nitrile, product safety is of great importance to the Malaysian glove industry. MREPC also works closely with standard setting and regulatory authorities such as the American Society for Testing and Materials (ASTM) and the U.S. Food and Drug Administration (FDA), as well as with other governmental organizations, and trade, consumer and public interest groups.

#### References

- 1) "Latex sensitization: Occupational versus general population prevalence rates." . Liss, G.M. and Sussman, G.L., American Journal of Industrial Medicine, 1999; 35: 196-200.
- 2) "Impact of Converting to Powder-free Gloves: Decreasing Symptoms of Latex Exposure in Operation Room Personnel." D. M. Korniewicz, N. Chookaew, J. Brown, N. Bookhamer and M.E. Bollinger. J AAOHN, 2005; 53(2): 1-6.
  - "Conversion to Low Protein, Powder-free Surgical Gloves. Is it Worth the Cost?" Korniewicz D.M., Chookaew N., El- Masri M., Mudd K., and Bollinger M.E., Journal AAOHN, 2005; 52(9): 388-393.
  - "A Significant Decrease in the Incidence of Latex-allergic Health Care Workers Parallels with a Decreasing Percentage of Highly Allergenic Latex Gloves in the Market in Finland" Reunala T, Turjanmaa K, Alenius H, Reinikka-Railo H, Palosuo T. J. Allergy Clin. Immunology, 2004; 11(2): Supplement: Abstract 140.
  - "A Four-Year Prospective Study to Evaluate the Efficacy of Glove Interventions in Preventing Natural Latex Sensitization in Healthcare Workers at Two Hospitals." Kelly, K.J., Klancnik, M., Kurup, V., Barrios-Jankol, C., Fink, J.N. and Petsonk, E.L. J. Allergy Clin. Immunol. 2003, Part 2; Vol. 111, No. 2, No. 426.
  - "Primary Prevention of Natural Rubber Latex Allergy in the German Health Care System Through Education and Intervention." Allmers, H., Schmengler, J. and Skudlik, C. J. Allergy Clin. Immunol. 2002; 110(2): 318-323.
  - "Management of Occupational Allergy to Natural Rubber Latex in a Medical Center: The Importance of Quantitative Latex Allergen Measurement and Objective Follow-up." Hunt, L.W., Kalker, P., Reed, C.E. and Yunginger, J.W. J. Allergy Clin. Immunol. 2002; 110: S94-106.
  - "Long-term Outcome of 160 Adult Patients with Natural Rubber Latex Allergy." Turjanmaa, K., Kanto, M., Kautiainen, H., Reunala, T. and Palosuo, T.J. Allergy Clin. Immunol. 2002; 110: S70-74.
  - "Outcomes of a Natural Rubber Latex Control Program in an Ontario Teaching Hospital." Tarlo, S.M., Easty, A., Dubanks, K., Min, F., and Liss, G. University Health Network and Department of Medicine and Public Health Sciences, University of Toronto. J. Allergy Clin. Immunol. 2001; 108: 628-633.
  - "Parameters of Natural Rubber Latex [NRL] Sensitization Decrease in Healthcare Workers (HCW) Following Reduction of NRL Exposure." Rueff, F. Schopf, P. and Przybilla, B. Klinik und Poliklinik fur Dermatologie und Allergologie, Ludwig-Maximilians-Universitat, Munich, Germany. Presented at the 56th annual meeting of the American Academy of Asthma, Allergy and Immunology (AAAAI) in 2000.
  - "Reduction of Latex Aeroallergens and Latex-specific IgE Antibodies in Sensitized Workers After Removal of Powdered Natural Rubber Latex Gloves in a Hospital." Allmers, H., Brehler, R. Chen. Z., Raulf-Heimsoth, M., Fels, H., and Baur, X.J. Allergy Clin.Immunol. 1998; 102: 841-846.
- 3) Stephanie Strom (January 4, 2013). "F.D.A. Offers Sweeping Rules to Fight Food contamination". New York Times. Retrieved 2013-01-05. One in six Americans becomes ill from eating contaminated food each year, the government estimates; of those, roughly 130,000 are hospitalized and 3,000 die.
- 4) "Integrity of Vinyl and Latex Procedure Gloves." Korniewicz, D.M., Laughon, B.E., Butz, A. and Larson, E. Nur. Res., 1989; 38:144-6.
  - "Leakage of Latex and Vinyl Exam Gloves in High and Low Risk Clinical Settings." Korniewicz, D.M., Kirwin, M., Crsci, K. and Larson, E. J. Am. Ind. Hyg. Assoc., 1993; 54: 22-26.
  - "Barrier Protection with Examination Gloves: Double versus Single." Korniewicz, D.M., Kirwin, M., Cresci, K., Tian Seng and Tay, E.C., Wool, M. and Larson, E. American Journal of Infection Control, 1994; 22(1): 12-15.
  - "Performance of latex and non-latex medical examination gloves during simulated use." Korniewicz, D.M., El-Masri, M., Broyles, J.M., Marin, D.C. and O'Connell, K.P. Am. J. Infect, Control, 2002; 30; 133-138.
  - "The permeability of dental procedure and examination gloves by an alcohol based disinfectant.". Baumann, M.A., Rath, B., Fischer, J.H. and Iffland, R. Dent. Mater., 2000; 16(2): 139-144.
- 5) Latex Allergy Latex Cross-reactive foods. Fact Sheet. American Latex Allergy Association /8-09
- 6) Latex-Food Cross-Reactivity. http://latexallergyresources.org/cross-reactive-food.

- 7) Executive summary of the meeting of the Additives and Ingredients Subcommittee of the Food Advisory Committee, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Aug. 26-27, 2003, Washington, D.C.
- 8) Beezhold et. al. Allergy Asthma Proc. 2000 Sep-Oct., 2(5), 301-6,
- "Fatalities due to anaphylactic reactions to foods." J. Allergy and Clinical Immunology, 2001; 107:191-193.
- **10)** "Di(2-ethylhexyl) phthalate contamination of retail packed lunches caused by PVC gloves used in the preparation of foods." Tsumura, Y., Ishimitsu, S., Kaihara, A., Yoshii, K., Nakamura, Y. and Tonogai, Y. Food Addit. Contam., 2001 Jun; 18(6): 569-579.
- **11)** . "A cancer risk assessment of di(2-ethylhexyl) phthalate; application of the new US EPA risk assessment guidelines." Doull, J. et. al Regulatory Toxicology and Pharmacology, 1999; 29: 327-357.
- **12)** "Oral toxicity of DEHP during pregnancy and suckling in the Long Evan rat." Arcadi, R.A. et. al. Food and Chemical Toxicology, 1998; 36: 963-970
- **13)** "Di(2-ethylhexyl) phthalate suppresses estradiol and ovulation in cycling rats." Davis, B.J. et. al. Toxicol. Appl. Pharmacol., 1994, 128: 216-223.
- 14) "Receptor and non-receptor mediated organ specific toxicity of DEHP in peroxisome proliferator-activated receptor alpha-null mice." Ward, J.M., et. al. Toxicology and Pathology, 1998; 26: 240-246.
- 15) "Hepatic effects of a phthalate ester plasticizer leached from poly(vinyl chloride) blood bags following transfusion" Kevy, S. and Jacobson, M. Environmental Health Perspectives, 1982; 45: 57-64.
- **16)** "DEHP as plasticizer in PVC respiratory tubing systems: indications of hazardous effects on pulmonary function in mechanically ventilated, preterm infants." Roth, B. et. al. European Journal of Pediatrics, 1998; 147: 41-46.
- 17) "Hypotension and cardiac arrest in rats after transfusion of mono(2-ethylhexyl) phthalate (MEHP) a contaminant of stored blood." Rock, G. et al. The New England Journal of Medicine, 1987; 316:1218-1219.
- 18) "Public Health Notification: PVC Devices Containing the Plasticizer DEHP," July 12, 2002.
- 19) Japan Ministry of Health, Food Chemical Unit of the Bureau of Hygiene, June 14, 2000.
- 20) "Health Officials In Japan Eye Ban on Vinyl Gloves," Asahi News Service, May 6, 2000